K043047

JAN - 7 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City UT 84121
Phone: (800) 874-6251; (801) 568-7000; Fax: (801) 568-7711

DEVICE NAME (Trade/common, and classification): Dynatron® IBox™ Iontophoresis device.

1. Regulation Name: Iontophoresis device
   Classification: Class III
   Regulation Nos.: 890.5525
   Product Codes: EGJ

2. PREDICATE DEVICES:

   Iontophor-II, model 6110B, manufactured by Life-Tech, Inc. cleared under K863166.

   Dupel Iontophoresis Device, manufactured by Empi cleared under K915444

3. PERFORMANCE STANDARDS: 21 CFR section 1010 (Performance Standards for Electronic Products: General) does not designate iontophoresis devices under performance standards requirements.

4. DESCRIPTION: The Dynatron® IBox™ is an iontophoresis device that delivers direct current to a drug delivery electrode placed on the patient's skin. This current expedites the migration of ionic drug solutions through the skin into localized tissue.

   The Dynatron® IBox™ is a battery powered, solid state, microprocessor-controlled unit that delivers measured, displayed direct current as defined by the user. Treatment duration is also measured and displayed.

   The device connects to any number of existing electrodes cleared for marketing in the United States that have a common snap connection. Device output is functionally identical to predicate devices.

5. INTENDED USE/INDICATIONS FOR USE: The Dynatron® IBox™ is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.

   The Intended Use/Indications For Use stated herein are consistent with the cleared indications for the predicate devices.

The following information is provided in support of this pre-market notification.

1.0 DEVICE IDENTIFICATION

1.1. TRADE NAME: Dynatron® IBox™

1.2 COMMON NAME: Iontophoresis device

1.3 REGULATION NUMBER: 890.5525

1.4 PRODUCT CODE: EGJ

1.5 CLASSIFICATION: Class III

1.6 PANEL: Physical Medicine

2.0 MANUFACTURER/SPONSOR INFORMATION:

2.1 MANUFACTURER: DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City, UT 84121
Phone: (800) 874-6251; (801) 568-7000
Fax: (801) 568-7711

2.2 ESTABLISHMENT REGISTRATION NUMBER: 1719362

2.3 SUBMISSION CORRESPONDENT: Ron Hatch
VP Operations/Regulatory Affairs
DYNATRONICS CORPORATION
7030 Park Centre Drive
Salt Lake City, UT 84121

3.0 PERFORMANCE STANDARDS:

21 CFR section 1010 (Performance Standards for Electronic Products: General) does not designate iontophoresis devices under performance standards requirements.

4.0 INTENDED USE/INDICATIONS FOR USE:

The Dynatron® IBox™ is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.

5.0 DEVICE DESCRIPTION:

The Dynatron® IBox™ is an electrophoresis device that delivers direct current to an electrode placed on the patient's skin. This current expedites the migration of ionic drug solutions through the skin into localized tissue.

The Dynatron® IBox™ is a battery powered, solid state, microprocessor-controlled unit that delivers measured, displayed direct current flow as defined by the user. Treatment duration is also measured and displayed.

The device connects to any number of existing drug delivery electrodes that have a common snap connection. Device output is functionally identical to predicate devices.

6.0 PROPOSED LABELING:

A label with statement "Caution. Federal law restricts this device to sale or by the order of a licensed practitioner" will appear on the device.

Copies of the Operator's Manual – Instructions for Use are submitted as an attachment (Appendix II).

7.0 PREDICATE DEVICE INFORMATION:

The proposed Dynatron® IBox™ is substantially equivalent to Iontophor-II model 6110, cleared under under K863166; and to Microphor, cleared under K913601; and to RH-900, cleared under K031115.

Evidence of Substantial Equivalence determination for the predicate devices is included in Appendix I.

The above cleared 510(k)s determined that these products, both hardware and software, were substantially equivalent (SE) to devices already in interstate commerce; hence, these products become the predicate devices for this submission.

No changes from the intended uses of the cleared predicate devices are claimed .

8.0 SUBSTANTIAL EQUIVALENCE:

The Dynatron® IBox™ is a variant of previously cleared iontophoresis devices, as follows:

Iontophor-II, model 6110, manufactured by Life-Tech, Inc. cleared under K863166.

Dupel Iontophoresis Device, manufactured by Empi cleared under K915444

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2005

Mr. Ronald J. Hatch
VP Operations/Regulatory Affairs
Dynatronics Corporation
7030 Park Centre Drive
Salt Lake City Utah 84121

Re: K043047
Trade/Device Name: Dynatron® IBox™ Iontophoresis Device
Regulation Number: 21 CFR 890.5525
Regulation Name: Iontophoresis device
Regulatory Class: III
Product Code: EGJ
Dated: November 1, 2004
Received: November 4, 2004

Dear Mr. Hatch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act), as long as you comply with all of the Act's requirements relating to drugs labeled or promoted with the devices as described below. You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Our substantially equivalent decision does not apply to the drugs that you will label or promote for use with your device. Therefore, you may neither label nor promote your device for use with specific drugs, nor package drugs with your device prior to FDA having approved the drugs for iontophoretic administration. For information on the requirements for marketing new drugs, you may contact:

Director
Division of Drug Labeling Compliance (HFD-310)
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland

As you are aware, iontophoresis devices that are intended to use a direct current to introduce ions of soluble salts or other drugs into the body and induce sweating for use in the diagnosis of cystic fibrosis or for other uses, if the labeling of the drug intended for use with the device bears adequate directions for the device's use with that drug, were classified into Class II. An iontophoresis device that is intended to use a direct current to introduce ions of soluble salts or other drugs into the body for medical purposes other than those specified for class II devices is classified into Class III (21 CFR 890.5525). We published our strategy for calling for premarket approval (PMA) applications in the enclosed Federal Register, dated May 6, 1994, and the enclosed memorandum, dated April 19, 1994, and the enclosed Federal Register, dated August 22, 2000.

If you have any questions regarding this letter, you may contact:

Kevin Lee, M.D.
Food and Drug Administration
Center for Devices and Radiological Health
Division of General, Restorative and Neurological Devices
9200 Corporate Boulevard (HFZ-410)
Rockville, Maryland 20850
(301) 594-1296

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation, please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by

reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number (if known): _____

Device Name: Dynatron® IBox™

Indications for Use:

The Dynatron® IBox™ is intended to use a direct current to introduce ions of soluble salts or other drugs into the body.

Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043047